



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,532	03/20/2001	David Allen Schul	26416.04598	2563

24024 7590 12/14/2006

CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,532	Applicant(s) SCHUL ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-63 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-63 and 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the remarks submitted September 12, 2005 and July 10, 2006, as well as in response to the pre-appeal conference of November 3, 2006. The conferees of the pre-appeal conference agreed that the previous rejections of record should be withdrawn and prosecution of the case should be re-opened.

In particular, the conferees agree with Applicants' arguments regarding the rejections of the claims over the teachings of Erickson in view of Miettinen et al. and Wester. Erickson is directed to the preparation of "clear" oils, whereas Miettinen et al. exemplifies only "non-clear" substances, such as margarine, having a percent by weight of the sterol ester as claimed. Accordingly, the teachings of Erickson can be construed as "teaching away" from the use of parameters such as a percent by weight of sterol ester that results in non-clear substances, as in the margarine composition of Miettinen et al, and thus the teachings of Erickson and percent by weight teachings of Miettinen et al. cannot be properly combined. The previous rejections of the claims over Erickson, Miettinen et al. and Wester et al. and therefore being withdrawn.

However, upon further consideration, new grounds of rejection are being made as set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the claims do not recite the units of the quantity to which the percentages are intended to refer. For example claim 57 recites "more than 10% and up to 30% of a sterol fatty acid ester," and "more than 50% monounsaturated fatty acid (MUFA) moiety," but does not specify whether these percentages are intended to refer to a percent by weight of the composition, or a percent by mole of the composition, or some other quantity. Accordingly, as the metes and bounds of the claims cannot be determined, the claims are rejected as being indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction and/or clarification is required.

In the interests of compact prosecution and for the purposes of applying prior art, the recited percentages are being interpreted as referring to the percentages by weight of the claimed components.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1617

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 60, 63 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,751,569 to Erickson, issued August 7, 1973.

Erickson teaches clear cooking and salad oils (edible oils) having hypercholesterolemic properties, where the oils have added thereto a plant sterol monocarboxylic acid ester (see abstract and column 1, lines 55-65, in particular.) Erickson teaches that the plant sterol ester can be added in a free sterol equivalent of from 0.5% to 10% (see column 1, lines 55-65, in particular.)

Erickson exemplifies compositions having sterol esters in the form of Beta-sitosteryl oleate added to an oil (see Table 1, in particular), and thus teaches sterol esters having more than 50% monounsaturated fatty acid, as oleic acid is a MUFA. Erickson further exemplifies the sterol ester added in an amount of 8% by weight, calculated as the free sterol equivalent, and thus teaches providing the sterol ester in an amount exceeding 10% by weight, as required by claim 57. In particular, the Examiner notes that Erickson's percent by weight calculated as the "free sterol equivalent" is being interpreted to mean that the value is equal to the percent by weight of the sterol moiety of the ester, as opposed to the percent by weight of the entire sterol ester. The oleic acid moiety of Erickson's sterol ester has a molecular weight that is approximately

Art Unit: 1617

70% of the molecular weight of the sterol moiety. Accordingly, it follows that a composition having 8 percent by weight of the sterol moiety of the sterol ester (free sterol equivalent) would have a percent by weight of the entire sterol ester of about 14% by weight, which meets the limitation of being "more than 10%" as recited in claim 57.

Accordingly, claim 57 is anticipated by the teachings of Erickson.

Regarding the recitation in claim 57 that the edible oil remains clear upon addition of the sterol fatty acid ester, it is noted that Erickson specifically teaches that the cooking and salad oils are "clear" (see abstract, in particular), and thus teaches this limitation.

Regarding the recitation in claim 57 that the edible oil "is free of solids at temperatures of greater than 60°F," it is noted that Erickson teaches that the oils are "clear" and can also be "cooking oils," and thus are presumably free of solids at cooking and other temperatures, such as greater than about 60°F. However, it is further noted that as Erickson teaches the claimed composition, the property of such a claimed composition will also be taught by the prior art, since the properties, namely the clarity and lack of solids, are inseparable from its composition. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess same properties as the instantly claimed product.

Art Unit: 1617

Erickson also meets the limitation of having less than about 6% of the fatty acid moieties being saturated fatty acids, as recited in claim 60, and less than 50% of the fatty acid moieties being polyunsaturated acids, as recited in claim 63, because Erickson's exemplified composition contains only oleic acid moieties (a monounsaturated fatty acid.)

Regarding claim 69, it is noted that as Erickson exemplifies a composition having about 14% by weight of sterol ester, Erickson teaches a composition having "up to", i.e. less than 30% of the sterol fatty acid ester, as recited in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58-59, 61-62 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,751,569 to Erickson, issued August 7, 1973.

Erickson is applied as discussed for claims 57, 60 and 63 above, and teaches a clear cooking or salad oil having sterol esters in an amount of more than 10% by weight, and exemplifies a composition having more than 10% by weight of an oleic acid ester of a sterol, and thus having more than 50% of a monounsaturated fatty acid moiety.

Erickson does not specifically exemplify a composition having the claims percents by weight of MUFAs or SFAs, as recited in claims 58-59 and 61-62. Erickson also does not specifically teach that the composition has an unesterified sterol level that meets the percentage ranges as recited in claims 65-68.

However, it is noted that Erickson teaches that various monocarboxylic acid moieties can be used in the sterol esters, including saturated monocarboxylic acids moieties containing from 1 to 12 carbon atoms (and thus saturated fatty acids), as well as unsaturated monocarboxylic acid moieties containing up to 24 carbon atoms (unsaturated fatty acids) (see column 2, lines 8-18, in particular.) Erickson also exemplifies sterol esters made with oleic acid as well as hexanoate, decanoate, laurate and palmitate moieties (saturated fatty acids) (see column 5, lines 15-25, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to form sterol esters containing both saturated and unsaturated fatty acid moieties, because Erickson teaches that both types of fatty acid moieties are suitable for the clear oil compositions. Regarding the amount of each of the saturated fatty acid and monounsaturated fatty acids provided, it is noted that it is

Art Unit: 1617

considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the fatty acids provided in the composition, according to the guidance provided by Erickson, to provide a composition having desired properties, such as a desired solubility and hypercholesterolemic activity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claims 58-59 and 61-62 are considered to be obvious over the teachings of Erickson.

Regarding the unesterified sterol level, it is noted that Erickson is directed to the desirability of providing the esterified form of the sterols in the cooking oils (see abstract, in particular), and also teaches that it is known to add plant sterols themselves (unesterified sterols) to compositions to provide hypocholesterolemic properties (see Background, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the esterified sterol with respect to the amount of unesterified sterol provided in the composition, according to the guidance provided by Erickson, to provide a composition having desired properties, such as desired oil solubility and hypocholesterolemic effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235

Art Unit: 1617

(CCPA 1955.) Accordingly, claims 56-67 are considered to be obvious over the teachings of Erickson.

Regarding claim 68, it is noted that Erickson exemplifies a composition with an oleic acid ester derivative of a sterol (see Table I, in particular), as has been discussed above, and thus meets the limitation of an edible oil having more than about 10% of a sterol fatty acid ester composition having more than 50% monounsaturated fatty acids, less than 6% saturated fatty acids, and less than 50% polyunsaturated fatty acids. Furthermore, as discussed above, it is considered obvious to optimize and/or vary the amount of the esterified sterol compared to the unesterified sterol provided in the composition, and thus the unesterified sterol level of less than about 10% is considered to be obvious over Erickson.

Regarding the recitation in claim 68 that the edible oil "is free of solids at room temperature," it is noted that Erickson teaches that the oils are "clear" and can also be "cooking oils," and thus are presumably free of solids at cooking and other temperatures, such as room temperature. However, it is further noted that as Erickson renders obvious the claimed composition, the property of such a claimed composition is also rendered obvious, since the properties, namely the clarity and lack of solids, are inseparable from its composition. Therefore, if the prior art teaches or renders obvious the composition, then the properties are also taught and/or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See

Art Unit: 1617

MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess same properties as the instantly claimed product.

Claims 57-59, 63, 65-67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/01126 to Van Amerongen et al, published January 15, 1998, in view of U.S. Patent No. 5,518,753 to Bracco et al, issued May 21, 1996.

Van Amerongen et al. teaches providing a composition having sterols that are esterified with a mixture of fatty acids (see abstract, in particular.) Van Amerongen et al. teaches that it is known that sterol ester derivatives can be provided to impart cholesterol lowering benefits (see page 1, lines 5-35, in particular.) Van Amerongen teaches that the sterol esters can be added to food products such as cooking and frying oils (see page 11, lines 15-30, in particular), and thus teaches adding the sterol esters to "edible oils" as recited in claim 57.

Regarding the percent by weight of the sterol ester added to the composition, as recited in claim 57, Van Amerongen et al. teaches that the esters can be added in an amount of from 0.5 to 40% by weight, which closely overlaps with the range of "more than 10% and up to 30% of a sterol ester composition." Furthermore, it is noted that it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the sterol ester provided in the composition, according to the guidance provided by Van Amerongen, to provide a

Art Unit: 1617

composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Van Amerongen et al. teaches that the sterols are preferably esterified with C₂₂-C₂₂ fatty acids (see page 8, lines 30-36, in particular), and that naturally occurring fat or oils can be used as the source of fatty acids (see page 9, lines 15-30, in particular.) Van Amerongen et al. further teaches that the fatty acid mixture used for esterifying can be chosen the basis of the fatty acids being capable of providing good blood cholesterol lowering itself, and suggest the use of an oil having "high amounts" (i.e. greater than 35%) of a polyunsaturated fatty acid (see page 9, lines 20-30, in particular), and teaches that sources of fatty acids including rice bran oil, sunflower, safflower, rapeseed, linseed, linola and/or soybean oil can be used, which are sources of "high" polyunsaturated fatty acids and/or low saturated fatty acids (see page 9, lines 30-35, in particular.)

Van Amerongen et al. does not specifically teach that the sterol ester composition contains more than 50% monounsaturated fatty acid moieties, as recited in claim 57.

Bracco et al. teaches an edible fatty acid triglyceride mixture (oil mixture) that contains from 50 to 70% by weight of monounsaturated fatty acids, up to 10% by weight of saturated fatty acids, and from 30% to 40% by weight of polyunsaturated fatty acids (see abstract, in particular.) Bracco et al. teaches that the lipidic composition is based on a combination of oils that are treated to provide good physiological performance qualities with an optimal balance of active substances to avoid unbalanced metabolic loads (see column 1, lines 50-56, in particular.) In particular, Bracco et al. teaches that monounsaturated fatty acids have a favorable effect on reduction of the cholesterol of the troublesome low-density lipoproteins (see column 1, lines 35-40), whereas saturated fatty acids can increase cholesterol levels (see column 1, lines 25-30, in particular), and an excessively high content of polyunsaturated fatty acids is undesirable due to their negative effects on cholesterol levels (see column 1, lines 30-35, in particular.) Bracco does, however, teach that certain polyunsaturated fatty acids, such as linolenic acid, can be desirably incorporated into the compositions (see column 1, lines 40-48 and column 2, lines 45-55, in particular.) Bracco et al. teaches that oils that are rich in oleic acid (a MUFA) include hybrids of sunflower and safflower oil (greater than 60% by weight oleic acid) (see column 2, lines 30-36, in particular.) Accordingly, it is considered that Bracco teaches that providing fatty acids having a majority by weight of monounsaturated fatty acids, such as from 50 to 70% by weight, provides cholesterol lowering and other health benefits, and also teaches that lipidic compositions having a desired fatty acid content can be prepared.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the high monounsaturated fatty acid content oils of Bracco et al. as the source of the fatty acids for the sterol esters of Van Amerongen et al, because Van Amerongen et al. teaches that the oils used as the source of fatty acids for the sterol esters can be selected according to the health benefits the fatty acids are capable of imparting, such as cholesterol lowering benefits, whereas Bracco et al. teaches that oils can be prepared having a high content of monounsaturated fatty acids, which are capable of imparting health benefits such as cholesterol lowering benefits. Thus, one of ordinary skill in the art would have been motivated to provide the lipidic composition having the high content of monounsaturated fatty acids as the source of fatty acids for the sterol esters of Van Amerongen et al, with the expectation of forming a sterol ester composition capable of providing cholesterol lowering benefits.

Regarding the recitation that the sterol ester composition contains "more than 50% monounsaturated fatty acid (MUFA) moieties", as recited in claim 57, it is noted that Bracco et al. teaches providing a composition with an excess, according to percent by weight, of monounsaturated fatty acids, such as from 50% to 70% by weight of the monounsaturated fatty acids, as has been discussed above, and also teaches the cholesterol lowering benefits of the monounsaturated fatty acids. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the content of the monounsaturated fatty

Art Unit: 1617

acids provided in the composition, according to the guidance provided by van Amerongen et al. and Bracco et al, to provide a composition having desired properties, such as desired cholesterol lowering activity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claim 57 is considered to be obvious over the teachings of Amerongen et al. and Bracco et al.

Regarding the recitation that the oil is "clear upon addition of the sterol fatty acid ester" and is "free of solids at temperatures of greater than about 60°F", it is noted that as the combined teachings of Van Amerongen et al. and Bracco et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the clarity and lack of solids, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claims 58-59, it is noted that, as discussed above, Bracco et al. teaches providing monounsaturated fatty acids in a majority amount of from 50 to 70%

Art Unit: 1617

by weight, and teaches the cholesterol lowering benefits imparted by such fatty acids. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the content of the monounsaturated fatty acids provided in the composition, according to the guidance provided by van Amerongen et al. and Bracco et al, to provide a composition having desired properties, such as desired cholesterol lowering activity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 63, Bracco et al. teaches that the polyunsaturated fatty acids can be provided in an amount of from 30% to 40% (see abstract, in particular), and Van Amerongen teaches that the polyunsaturated fatty acids can be provided in an amount of greater than 35% (see page 9, lines 20-30, in particular.) Bracco et al. further teaches that polyunsaturated fatty acids in general have negative effects on cholesterol levels, although select PUFAs can be beneficial to cholesterol levels, such as linolenic acid, as has been discussed above. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the content of the polyunsaturated fatty acids provided in the composition, according to the guidance provided by van Amerongen et al. and Bracco et al, to provide a composition having desired properties, such as desired cholesterol lowering activity. It is noted that "[W]here the general conditions of a claim are

Art Unit: 1617

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 65-67, Van Amerongen et al. teaches that the conditions of esterification are desirably selected such that at least 50%, and preferably 90-100% by weight of the sterols are esterified, and thus teaches esterification levels that overlap with the ranges as recited in the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of esterified sterol and/or unesterified sterol provided in the composition, according to the guidance provided by Van Amerongen et al. and Bracco et al, to provide a composition having desired properties, such as desired cholesterol lowering properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 69, it is noted that Van Amerongen et al. teaches that the esters can be added in an amount of from 0.5 to 40% by weight, which closely overlaps with the range of "up to 30% of a sterol ester composition." Furthermore, it is noted that it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the sterol ester provided in

Art Unit: 1617

the composition, according to the guidance provided by Van Amerongen, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 60-62 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/01126 to Van Amerongen et al, published January 15, 1998, in view of U.S. Patent No. 5,518,753 to Bracco et al, issued May 21, 1996, as applied to claims 57-59, 63, 65-67 and 69 above, and further in view of EP 0 679 712 to Cain et al, published November 2, 1995.

Van Amerongen et al. and Bracco et al. are applied as discussed above, and render obvious an edible oil composition having a sterol ester composition in an amount of more than 10% by weight, with more than 50% monounsaturated fatty acid moieties, as has been discussed above. Van Amerongen et al. and Bracco et al. further render obvious the composition having less than 50% polyunsaturated fatty acids and a level of unesterified sterol of less than about 10%, as recited in claim 68.

Van Amerongen et al. and Bracco et al. do not specifically teach the fatty acids comprising less than about 6% saturated fatty acid, as recited in claims 60 and 68, or the lower saturated fatty acid levels of claims 61-62. However, Bracco et al. does teach

Art Unit: 1617

the desirability of providing a composition having less than 10% of saturated fatty acids, as these fatty acids have undesirable effects on cholesterol levels (see abstract and column 1, lines 25-30, in particular.)

Cain et al. teaches that oils having a saturated fatty acid content of less than 5% can be obtained by conversion of the oils and separation of the higher melting saturated fatty acid-containing products (see abstract, in particular), and further teaches that a SFA content of less than 3% by weight can be achieved (see page 3, lines 25-32, in particular), accordingly, Cain et al. teaches that oils having reduced amounts of saturated fatty acids can be prepared, such as amounts that meet and/or overlap with the range limitations as recited in claims 60-62 and 68.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to perform the SFA reducing process to Cain et al. to reduce the amount of SFAs in the oil used for the sterol ester of Van Amerongen et al. and Bracco et al, because Van Amerongen et al. and Bracco et al. teach the desirability of using low amounts of SFAs, such as less than 10%, to reduce negative effects on cholesterol, and Cain et al. teaches methods by which low concentrations of SFAs in an oil can be achieved. Thus, one of ordinary skill in the art would have been motivated to perform the SFA reducing method to provide an oil having a reduced amount of SFA for the sterol ester composition of Van Amerongen et

Art Unit: 1617

al. and Bracco et al, with the expectation of providing an oil suitable for forming the sterol composition and provide cholesterol lowering effects.

Regarding the specific weight percent ranges as recited in claims 60-62 and 68, it is noted that Cain teaches providing less than 3% by weight of SFA in the composition, which meets and/or overlaps with the ranges as recited in the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the SFAs provided in the composition, according to the guidance provided by Van Amerongen et al, Bracco et al and Cain et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claims 60-62 and 68 are considered to be obvious over Van Amerongen et al, Bracco et al. and Cain et al.

Regarding the recitation in claim 68 that the edible oil "is free of solids at room temperature," it is noted that, as Van Amerongen et al, Bracco et al. and Cain et al. renders obvious the claimed composition, the property of such a claimed composition is also rendered obvious, since the properties, namely the clarity and lack of solids, are inseparable from its composition. Therefore, if the prior art teaches or renders obvious the composition, then the properties are also taught and/or rendered obvious by the

Art Unit: 1617

prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess same properties as the instantly claimed product.

Response to Arguments

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

No claims are allowed.

The prior art being made of record and not relied upon that is considered pertinent to applicant's disclosure is listed on the accompanying PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

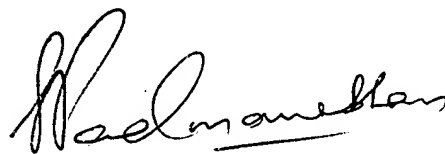
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

Art Unit: 1617

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER